CLAIMS

1) A crystallisation process comprising:

a) dissolving the substance to be crystallised in a medium wherein the viscosity of the medium can be adjusted;

b) applying a means for adjusting the viscosity of the medium until a gel with an apparent viscosity in the range 25 to 90 Pa.s at a shear rate of $1s^{-1}$ is reached;

c) allowing crystal growth;

d) applying a means for adjusting the viscosity of the medium until a fluid with an apparent viscosity less than 25 Pa.s at a shear rate of $1s^{-1}$ is reached; and

e) harvesting the crystals.

2) A crystallisation process as claimed in claim 1, wherein the means for adjusting the viscosity of the medium is temperature change, ultrasound, thixotropicity, electro-rheology, mechanical shear, chemical additive, or pH change.

3) A crystallisation process as claimed in claim 2 wherein the means for adjusting the viscosity of the medium is pH change.

4) A crystallisation process as claimed in ~~any preceding claim~~ Claim 1 wherein the medium is an aqueous solution of a Carbomer.

5) A crystallisation process as claimed in claim 4, wherein the Carbomer is Carbopol 934™.

6) A crystallisation process as claimed in ~~any preceding claim~~ wherein the substance to be crystallised is a drug substance or a carrier for drug particles, suitable for use in an inhaled pharmaceutical composition.

7) A crystallisation process as claimed in ~~any preceding claim~~ wherein the substance to be crystallised is lactose, lactose monohydrate, salbutamol sulphate or ipratropium bromide.

8) A crystallisation process as claimed in ~~any preceding claim~~, wherein the crystals are harvested by means of collection by filtration.

9) A crystallisation process as claimed in ~~any preceding claim~~, wherein the process comprises:

a) dissolving the substance to be crystallised in an aqueous solution of a medium wherein the viscosity of the medium is pH-dependent;

b) adjusting the pH of the medium until a gel with an apparent viscosity in the range 25 to 90 Pa.s at a shear rate of $1s^{-1}$ is reached;

c) allowing crystal growth;

d) adjusting the pH of the medium until a fluid with an apparent viscosity less than 25 Pa.s at a shear rate of $1s^{-1}$ is reached; and

e) harvesting the crystals.

10) A process as claimed in claim 9 wherein the medium is an aqueous solution of a Carbomer.

11) A crystallisation process as claimed in claim 1 ~~or 2~~ wherein the substance to be crystallised is fluticasone propionate or salmeterol xinafoate

12) Lactose monohydrate crystals obtained according to the process as claimed in ~~any preceding claim.~~ Claim 1

13) Lactose monohydrate crystals as claimed in claim 12 for use in powder formulations for inhaled use.

14) Salbutamol sulphate, oxitropium bromide or ipratropium bromide crystals obtained according to the process as claimed in ~~any of claims 1 to 10.~~ Claim 1

15) Fluticasone propionate or salmeterol xinafoate crystals obtained according to the process as claimed in claim 1 ~~or 2.~~

16) Salbutamol sulphate, oxitropium bromide or ipratropium bromide crystals as claimed in claim 14 for use in powder formulations for inhaled use.

17) Fluticasone propionate or salmeterol xinafoate crystals as claimed in claim 15 for use in powder formulations for inhaled use.

18) A pharmaceutical formulation for administration by inhalation comprising lactose monohydrate crystals as claimed in claim 12 and/or salbutamol sulphate or ipratropium bromide crystals ~~as claimed in claim 14.~~

19 ~~18~~) A pharmaceutical formulation for administration by inhalation comprising lactose monohydrate crystals as claimed in claim 12 and/or fluticasone propionate or salmeterol xinafoate crystals ~~as claimed in claim 15.~~

Rule 126

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